

APPENDIX A

**STATEMENT OF
UNDISPUTED FACTS**

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC.,

Plaintiff,

vs.

BRAIN FREQUENCY LLC,

Defendant.

Civil Action No. 5:23-cv-00626-XR

Demand for Jury Trial

**DEFENDANT BRAIN FREQUENCY LLC'S STATEMENT OF UNDISPUTED
MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY
JUDGEMENT**

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and the Court's Local Rules, Defendant Brain Frequency LLC ("Brain Frequency") files this Statement of Undisputed Material Facts in Support of its Motion for Partial Summary Judgment pursuant to 35 U.S.C. § 287(c)(1) (the "Physician's Immunity Statute"). In support thereof, Brain Frequency would respectfully show the Court as follows:

Procedural Background

1. Plaintiff Wave Neuroscience ("Plaintiff") filed suit against Brain Frequency on May 15, 2022. [See Dkt. No. 1 ("Original Complaint").]
2. Plaintiff filed a second amended complaint on October 15, 2023 accusing Brain Frequency of patent infringement. [See generally Dkt. No. 10 ("Second Amended Complaint").]

The Asserted Patents and Claims

3. Plaintiff alleges that Brain Frequency infringes four patents, three of which contain asserted method claims, including: U.S. Patent Nos 10,029,111 (the "'111 Patent"); 8,465,408 (the

“‘408 Patent’); and 8,870,737 (the “‘737 Patent) (collectively the “Asserted Patents”).¹ [See generally Dkt. No. 10].

4. Plaintiff served its infringement contentions (“Infringement Contentions”) identifying its asserted claims for each of the Asserted Patents on December 15, 2023. [See Declaration of John Saba (“Saba Decl.”) at ¶ 7, Ex. 4.]

(The “‘111 Patent”)

5. The ‘111 Patent is entitled “RTMS At Harmonics of Biological Signals.” [Id. at ¶ 4, Ex. 1.]

6. Plaintiff alleges Brain Frequency infringes Claims 1 and 3-7 of the ‘111 Patent. [Id. at ¶ 8, Ex. 1; *see also id.*, Ex. 4.]

7. Claim 1 of the ‘111 Patent is an independent claim and Claims 3-7 are dependent claims. [Id.]

8. Claims 1 and 3-7 of the ‘111 Patent are all method claims. [Id.]

9. Each of the limitations of Claim 1 of the ‘111 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [See Declaration of Shannon Malish (“Malish Decl.”) at ¶¶ 16-17.]. For example, Claim 1 teaches “A method of improving a physiological condition or a neuropsychiatric condition [] which comprises [] repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric...” [See Saba Decl., Ex. 1 at Claim 1.]

10. Each of the limitations of dependent Claim 3 of the ‘111 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Malish Decl. at ¶¶ 16-17.]

¹ Plaintiff also asserts alleged infringement of United States Patent No. 8,926,490 (the “‘490 Patent”), which includes apparatus claims.

11. Each of the limitations of dependent Claim 4 of the '111 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Id.]

12. Each of the limitations of dependent Claim 5 of the '111 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Id.]

13. Each of the limitations of dependent Claim 6 of the '111 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Id.]

14. Each of the limitations of dependent Claim 7 of the '111 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Id.]

15. Plaintiff's allegations of infringement related to the '111 Patent include allegations of direct infringement pursuant to Section 271(a) and induced infringement pursuant to Section 271(b). [Second Amended Complaint at ¶¶ 55-60.]

16. Plaintiff's Second Amended Complaint does not contain any specific allegations or evidence of contributory infringement pursuant to Section 271(c). [Id.]

17. Plaintiff's Infringement Contentions do not assert contributory infringement pursuant to Section 271(c) with respect to the '111 Patent. [See Saba Decl., Ex 4.]

(The “'408 Patent”)

18. The '408 Patent is entitled “Systems and Methods For Modulating The Electrical Activity of a Brain Using Neuro-EEG Synchronization Therapy.” [Saba Decl., Ex. 2.]

19. Plaintiff alleges Brain Frequency infringes Claims 1-4, 9-10, 12, and 20 of the '408 Patent. [Id. at ¶ 9.]

20. Claims 1, 2, 12 of the '408 Patent are independent claims. [Id.]

21. Claims 3-4 and 9-10 and 20 of the '408 Patent are dependent claims. [Id.]

22. Claims 1-4 and 9-10 of the '408 Patent are all method claims. [Id.]

23. Each of the limitations of Claim 1 of the '408 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Malish Decl. at ¶¶ 16, 18.] For example, Claim 1 teaches “A method of treating Parkinson’s disease...[by] adjusting a setting of a magnetic field....[to] move an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band using the magnetic field....” [Saba Decl., Ex. 2 at Claim 1.]

24. Each of the limitations of Claim 2 of the '408 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Malish Decl. at ¶ 16-18.] For example, Claim 2 teaches “[a] method of treating Parkinson’s disease...comprising moving at least one of: an intrinsic frequency of a brain of the Subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band....” [Saba Decl., Ex. 2 at Claim 2.]

25. Each of the limitations of dependent Claim 3 of the '408 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Malish Decl. at ¶¶ 16, 18.]

26. Each of the limitations of dependent Claim 4 of the '408 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [*Id.*]

27. Each of the limitations of dependent Claim 9 of the '408 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [*Id.*]

28. Each of the limitations of dependent Claim 10 of the '408 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [*Id.*]

29. Plaintiff’s allegations of infringement related to the '408 Patent include allegations of direct infringement pursuant to Section 271(a) and induced infringement pursuant to Section

271(b). [Second Amended Complaint at ¶¶ 61-67.]

30. Plaintiff's Second Amended Complaint does not contain any specific evidence or allegations of contributory infringement pursuant to Section 271(c) of the '408 Patent. [*Id.*]

31. Plaintiff's Infringement Contentions do not assert contributory infringement pursuant to Section 271(c) with respect to the '408 Patent. [See Saba Decl., Ex 4.]

(The “’737 Patent”)

32. The '737 Patent is entitled “Systems and Methods for Neuro-EEG Synchronization and Therapy.” [Saba Decl., Ex. 3.]

33. Plaintiff alleges that Brain Frequency infringes Claims 1-4, 8-9, and 11 of the '737 Patent. [*Id.* at ¶ 10.]

34. Claims 1 and 2 of the '737 Patent are independent claims. [*Id.*]

35. Claims 3-4, 8-9, and 11 of the '737 Patent are dependent claims. [*Id.*]

36. Claims 1-4, 8-9, and 11 of the '737 Patent are all method claims. [*Id.*]

37. Each of the limitations of Claim 1 of the '737 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Malish Decl. at ¶¶ 16, 19.] For example, Claim 1 teaches “adjusting [the] output of a magnetic field; applying said magnetic field close to a head of a subject; and moving, using the magnetic field, at least one of an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency...wherein the pre-selected intrinsic frequency is a frequency that increases blood flow in the cortex of the subject.” [Saba Decl., Ex. 3 at Claim 1.]

38. Each of the limitations of Claim 2 of the '737 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Malish Decl. at ¶¶ 16, 19.] For example, Claim 2 teaches “adjusting [the] output of a magnetic field; applying said magnetic field

close to a head of a subject; and moving, using the magnetic field, an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency...wherein the pre-selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject.” [Saba Decl., Ex. 3 at Claim 2.]

39. Each of the limitations of dependent Claim 3 of the ’737 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [Malish Decl. at ¶¶ 16, 19.]

40. Each of the limitations of dependent Claim 4 of the ’737 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [*Id.*]

41. Each of the limitations of dependent Claim 8 of the ’737 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [*Id.*]

42. Each of the limitations of dependent Claim 9 of the ’737 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [*Id.*]

43. Each of the limitations of dependent Claim 11 of the ’737 Patent relate to the performance of a medical activity or procedure on a body by a medical practitioner. [*Id.*]

44. Plaintiff’s allegations of infringement related to the ’737 Patent include allegations of direct infringement pursuant to Section 271(a) and induced infringement pursuant to Section 271(b). [Second Amended Complaint at ¶¶ 68-73.]

45. Plaintiff’s Second Amended Complaint does not contain any specific allegations of contributory infringement pursuant to Section 271(c) of the ’737 Patent. [*Id.*]

46. Plaintiff’s Infringement Contentions do not assert contributory infringement pursuant to Section 271(c) with respect to the ’737 Patent. [See Saba Decl., Ex 4.]

Brain Frequency and the Accused Software

47. Brain Frequency provides software technology to assist with the treatment of individuals suffering from mental disorders and conditions including, trauma, post-traumatic stress disorder, addiction, depression and anxiety. [Malish Decl. at ¶ 4.]

48. Brain Frequency's founder, Shannon Malish, is a Licensed Clinical Social Worker ("LCSW") in the State of Texas and has years of experience treating and facilitating thousands of patients suffering from such mental disorders, including those with addiction, depression and PTSD. [*Id.* at ¶¶ 2-3, 5.] Over the course of years, Ms. Malish's treatments have included Transcranial Magnetic Stimulation ("TMS"), which is a widely-known therapy of providing magnetic stimulation to affected areas of the brain. [*Id.*]

49. Recognizing that TMS—in combination with a patient's EEG data—has historically provided positive results for mental therapy, Ms. Malish set out to improve the method. [*Id.* at ¶ 5.] After years of clinical research, Ms. Malish discovered certain patterns in areas of the brain (as measured by EEG data) correlating to certain mental disorders. [*Id.*]

50. Her efforts lead to the development of Brain Frequency's proprietary software (hereinafter the "Brain Frequency Software") which analytically diagnoses a patient's EEG measurements to more precisely indicate the areas of the brain of the patient that are negatively impacted. [*Id.*]

51. The Brain Frequency Software provides unique analytics of a patient's data in order to more efficiently diagnose and target how TMS should be used for much more effective results. [*Id.*]

52. Notably, Brain Frequency *only* provides software; it does not provide or sell machines, or parts or components of machines, such as TMS and EEG devices. [*Id.* at ¶¶ 10, 12.]

53. Brain Frequency *only* licenses the Brain Frequency Software to individual practitioners (MDs, *etc.*) or organizations that exclusively treat patients with medical disorders.

[*Id.* at ¶¶ 6-9.]

54. Further, the core purpose of the software is to assist doctors and clinicians with more effective diagnosis and treatments. [*Id.*]

55. Each of Brain Frequency's licensees are medical practitioners or those acting under the direction and supervision of medical practitioners who are licensed by the State of Texas to diagnose and treat medical patients. [*Id.*]

56. Exhibit 5 attached to the Declaration of Shannon Malish is a true and correct copy of an exemplar of the contractual agreements entered into between Brain Frequency and its licensees. [*Id.* at ¶ 7.]

57. Each of Brain Frequency's medical practitioner licensees provide medical diagnosis or treatment to medical patients using the Brain Frequency Software pursuant to the contractual agreements entered into between Brain Frequency and the medical practitioners. [*Id.* at ¶¶ 7-9.]

58. Pursuant to the contractual agreements between Brain Frequency and its licensees, the Brain Frequency Software is intended to be used exclusively for the purpose of engaging in medical activities, namely, the diagnosis and treatment of medical patients. [*Id.*]

59. The Brain Frequency Software is not a machine and is not used to manufacture patented machines, nor is it a composition of matter. It also does not involve the use of biological materials or clinical laboratory services. It is software. [*Id.* at ¶ 10.]

60. The Brain Frequency Software is not regulated, formally or officially, by the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Clinical Laboratories

Improvement Act, or the Food and Drug Administration. [*Id.* at ¶ 11.]

61. Brain Frequency does not make, sell, offer to sell, or market any products regulated by the Food and Drug Administration or any other regulatory agency. [*Id.* at ¶¶ 11-12.]

62. The appearance of Shannon Malish on the Longevity Podcast in November 2022 was for the purpose of providing educational information to medical practitioners and others about the benefits of using the Brain Frequency Software to diagnose and treat patients, not for the purpose of advertising, marketing, or promoting the Brain Frequency Software for commercial gain. [*Id.* at ¶ 13.]

63. The information available on Brain Frequency's website at <https://brainfrequency.ai/treatment-process> is for the purpose of providing educational information to medical practitioners and others about the benefits of using the Brain Frequency Software to diagnose and treat patients, not for the purpose of advertising, marketing, or promoting the Brain Frequency Software for commercial gain. [*Id.* at ¶ 14.]